IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ABBOTT GMBH & CO., KG, ABBOTT BIORESEARCH CENTER, INC., ABBOTT BIOTECHNOLOGY, LTD. Plaintiffs, v. CENTOCOR ORTHO BIOTECH, INC., CENTOCOR BIOLOGICS, LLC. Defendants.	C.A. No. 4:09-CV-11340 (FDS) JURY TRIAL DEMANDED ***(FILED UNDER SEAL)***

ABBOTT'S OPPOSITION TO CENTOCOR'S *DAUBERT* MOTION TO EXCLUDE EVIDENCE OF ALLEGED LOST PROFIT DAMAGES FROM ABBOTT EXPERT JULIE L. DAVIS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Federal Cases

Federal Rules

I. INTRODUCTION AND SUMMARY OF ARGUMENT

Abbott's damages expert is Julie L. Davis, a certified public account who has provided damages trial testimony in over 50 patent cases on behalf of plaintiffs and defendants. As is common in patent cases, her report concludes that Abbott is entitled to a mix of lost profits and reasonable royalty damages. Her lost profits calculation is based on Centocor's sale of the infringing product, Stelara, and Abbott's lost sales of Humira, a product that competes with Stelara for the treatment of psoriasis. Notably, Centocor does not challenge Ms. Davis's qualifications or her methodology. Indeed, Centocor's own damages expert also computed damages based on a mix of lost profits and reasonable royalties using the same methodology, albeit arriving at a smaller number.

Nonetheless, Centocor has moved to exclude Ms. Davis's lost profits opinion in its entirety based on two inputs to Ms. Davis's calculations. Centocor's motion should be denied because its challenges go at best to the weight of the evidence, not its admissibility.

First, Centocor challenges Ms. Davis's U.S. lost profits analysis as unreliable because she makes use of Wolters-Kluwer ("WK") data that tracks actual patient prescriptions nationwide.[1] According to Centocor, Ms. Davis is insufficiently familiar with the WK data set on which she relied and is therefore precluded from relying upon it. Centocor can make this challenge only by ignoring Ms. Davis's testimony setting forth her considerable knowledge of the data and explaining the reasons for her reliance on this well-known and established independent third-party data source. Centocor's own expert has relied on WK data in calculating damages in other cases, and Abbott relies on WK data in the ordinary course of business, including using it as a basis for paying royalties under a license from Centocor. Ms. Davis is not

[1] The WK database is now known as Source Healthcare Analytics ("SHA") following its acquisition by Symphony Technology Group earlier this year. (*See* Ex. 4, Supplemental Expert Report of Julie L. Davis, dated July 13, 2012, at 3 n.12.) For simplicity and consistency, Abbott refers to the SHA data as WK data in this Opposition brief.

required to be an "expert" on WK data; at best her experience or lack of experience with the data goes to the weight that should be given her testimony, not its admissibility.

Second, Centocor seeks to exclude Ms. Davis's lost profits analysis for sales made outside of the United States ("O.U.S.") due to her reliance on an explanation provided by a then-Abbott employee that O.U.S. patients are not switched between TNFα therapies. This challenge also goes to the weight of the evidence and is, in any event, moot. Nearly 80% of the damages incurred by Abbott as a result of Centocor's infringement has occurred since Ms. Davis's original report and deposition, and Ms. Davis has consequently filed a supplemental report addressing new information about Centocor's continuing infringement. Among the information that has become available to Ms. Davis is information indicating that patient switching, at a lower rate than in the United States, does occur to some extent outside of the U.S. Ms. Davis's supplemental damages report reflects this new information and now adopts a conservative approach using U.S. patient switching rates (*i.e.*, the WK data) to calculate O.U.S. lost profits.

II. RELEVANT FACTUAL BACKGROUND

A. Ms. Davis's U.S. Lost Profits Analysis Incorporates Independent Third-Party Wolters-Kluwer Data.

1. *Ms. Davis's Report*

Ms. Davis's lost profits analysis is based on the well-accepted framework set forth in *Panduit Corp. v. Dennison Manufacturing Co.*, 810 F.2d 1561 (Fed. Cir. 1987) and *State Industries, Inc. v. Mor-Flo Industries, Inc.*, 883 F.2d 1573 (Fed. Cir. 1989). *Panduit* establishes a frequently utilized test for determining whether lost profits are recoverable. Fundamentally, the lost profits analysis seeks to answer the question of whether the patentee would have made the infringer's sales "but for" the infringement.

Mor-Flo establishes that even if the patentee would not have made all of the sales made

by the infringer (because of the presence of other competitors), it may still recover lost profits damages by determining its percentage share of the market and calculating lost profits reflective of its overall market share. Using the market share approach to lost profits, infringing sales that are not subject to lost profits are subject instead to a reasonable royalty, and the total measure of damages is the combination of lost profits and reasonable royalty damages.

One of the components of Ms. Davis's U.S. lost profits analysis is WK data showing whether new Stelara patients are first-time biologic therapy users (*i.e.*, bio-naïve) or bio-experienced and identifying other biologic therapies used by bio-experienced patients before trying Stelara. (*See* Centocor Ex. 2, Expert Report of Julie L. Davis, dated May 16, 2011 ("Davis Rep."), at 33.) This information is then utilized, along with market share data, to calculate what Stelara sales would have instead been Humira sales if Stelara were never in the market.[2] The use of the WK data has a minor impact on the overall damages calculation by essentially dividing the market into bio-naïve and bio-experienced patients and subdividing the bio-experienced patients based on the biologic product they previously used. Because there is evidence indicating that Humira's market share is different in these segments, the amount assigned to each segment can affect the total lost profits figure. There is no authority suggesting that a lost profits calculation must fine tune the market analysis to this extent; however, because there is data available that potentially increases the accuracy of the analysis, Ms. Davis used the

[2] For Stelara patients who are bio-naïve, Ms. Davis re-allocates those Stelara sales among the other biologics according to their relative market share. For the segment of Stelara patients who are bio-experienced and have tried Enbrel but not Humira before starting on Stelara, Ms. Davis re-allocates those Stelara sales among other biologics excluding Enbrel (which would not be an alternative for such patients) according to their relative market shares. Likewise, Ms. Davis's analysis specifically accounts for Stelara patients who have previously tried Humira by removing them from her lost profits analysis irrespective of the reason why they are no longer Humira patients, *i.e.*, whethe [redacted] Ms. Davis includes these Humira "failures" in her reasonable royalty analysis since they would not be Humira patients "but-for" Stelara's presence in the market.

data to refine her calculations.

Wolters-Kluwer is a leading provider of information and analytics to the pharmaceutical, biotech, and medical device industries that is regularly relied on by Abbott to evaluate the market and to make business decisions. [redacted]

Critically, Centocor does not take issue with Ms. Davis' overall methodology. [redacted]

2. *Ms. Davis's Deposition*

Centocor seeks to exclude Ms. Davis's U.S. lost profits calculation is based on Ms. Davis's deposition and her purported lack of familiarity with WK data. According to Centocor, Ms. Davis merely relied on a "three-page PowerPoint she was provided by Abbott's

lawyers" that "allegedly" contains "Wolters-Kluwer data" while knowing "very little" about the PowerPoint or underlying data. (Centocor Mot. at 7, 10, 13; [redacted]

Centocor's allegations are both irrelevant and wrong. First, Ms. Davis's opinion is based on WK data used by Abbott in the ordinary course of business. In the course of preparing her first report, Ms. Davis considered two PowerPoint presentations that calculated the percentage of bio-naïve and bio-experienced patients. [redacted] As is evident from the face of the document, this report was created in the ordinary course of business in connection with Stelara's launch. I[redacted]

[redacted]

[3] This data has now been further updated in accordance with the Court's Pre-Trial Schedule, and produced in Abbott's Ju[redacted]ort incorporates the latest WK data. [redacted]

[redacted]

B. Ms. Davis's O.U.S. Lost Profits Analysis Applies U.S. Patient Switching Data, Thereby Generating A Conservative Damages Number Favorable To Centocor.

Centocor also challenges Ms. Davis's O.U.S. lost profits analysis [redacted] Based on this information, Ms. Davis did not attempt to segment the market based on whether Stelara patients were bio-naïve or bio-experienced (and whether they had already tried and failed Humira) in calculating O.U.S. lost profits in her initial report.[4]

After her deposition, while preparing a supplemental report in accordance with the Court's Pre-Trial Schedule, [redacted]

[4] [redacted]

[redacted]

The result reduces the O.U.S. lost profits figure compared to an analysis that would assume no-switching. Since Ms. Davis's O.U.S. lost profits analysis now overcompensates for any switching by applying the U.S. switching data, Centocor's challenge to Ms. Davis's O.U.S. lost profits analysis is no longer relevant.[5]

III. LEGAL STANDARD

Federal Rule of Evidence 702 governs the admissibility of expert testimony. This Court has held that "[t]he Rule 702 inquiry 'is a flexible one, and there is no particular procedure that the trial court is required to follow in executing its gatekeeping function.'" *Riani v. Louisville Ladder, Inc.*, No. 07-40258, 2010 WL 2802040, at *5 (D. Mass. July 14, 2010) (Saylor, J.) (quoting *United States v. Diaz*, 300 F.3d 66, 74 (1st Cir. 2002)).

As this Circuit and Court have recognized, a *Daubert* motion requires the Court to carefully evaluate whether the challenge to the expert testimony goes more to the weight, rather than the admissibility, of the proffered opinion. *See Allen v. Martin Surfacing*, 263 F.R.D. 47, 53 (D. Mass. 2009) (Saylor, J.) (citing *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998) (explaining the opinion rested upon good grounds generally and should be

[5] Centocor rejected Abbott's proposal that the parties file any *Daubert* motions relating to damages one week after the parties' exchange of supplemental damages reports, which would have taken into account the factual and financial data exchanged in discovery on June 29, 2012. (*See* Ex. 13, Letter R. Weiner to A. Verrecchio, dated June 22, 2012; Ex. 14, Letter A. Verrecchio to R. Weiner, dated June 25, 2012; Ex. 15, Email Exchange between A. Verrecchio and R. Weiner, dated June 29, 2012.)

tested by the "adversarial process"); *Mitchell v. United States,* 141 F.3d 8, 15 (1st Cir. 1998) (stating that expert's lack of specialty practice in the area about which he testified went to weight, not admissibility)). Indeed, challenges to the factual underpinnings of an expert's investigation "often go to the weight of the proffered testimony, not to its admissibility." *Crowe v. Marchand,* 506 F.3d 13, 18 (1st Cir. 2007).

Other circuit courts agree that challenges to assumptions go to the weight of the proffered testimony and not to admissibility. *See, e.g.*, *Synergetics, Inc. v. Hurst*, 477 F.3d 949, 955-56 (8th Cir. 2007) ("As a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination."); *In re TMI Litig.*, 193 F.3d 613, 665 (3d Cir. 1999) ("The test of admissibility is not whether a particular scientific opinion has the best foundation, or even whether the opinion is supported by the best methodology or unassailable research. … The goal is reliability, not certainty. Once admissibility has been determined, then it is for the trier of fact to determine the credibility of the expert witness.") (internal citation omitted); *United States v. 14.38 Acres of Land*, 80 F.3d 1074, 1077 (5th Cir. 1996) ("[I]n determining the admissibility of expert testimony, the district court should approach its task with proper deference to the jury's role as the arbiter of disputes between conflicting opinions. As a general rule, questions relating to the bases and sources of an expert's opinion affect the weight to be assigned that opinion rather than its admissibility and should be left for the jury's consideration.") (internal quotations omitted).

While the entitlement to lost profits is sometimes viewed as a question of law, *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995), the amount of damages and how they are calculated is clearly a fact question for the jury. *Lucent Techs., Inc. v. Gateway, Inc.*,

580 F.3d 1301, 1310 (Fed. Cir. 2009). But a patentee does not need to prove the amount of damages to the exact dollar. As the Federal Circuit explained in *Rite-Hite*, so long as there is a reasonable probability the patentee would have made the lost sales, it falls to the infringer to produce evidence of any lost sales that it contends would not have been captured by the patentee:

> A patentee need not negate every possibility that the purchaser might not have purchased a product other than its own, absent the infringement. The patentee need only show that there was a reasonable probability that the sales would have been made "but for" the infringement. When the patentee establishes the reasonableness of this inference, *e.g.,* by satisfying the *Panduit* test, it has sustained the burden of proving entitlement to lost profits due to the infringing sales. The burden then shifts to the infringer to show that the inference is unreasonable for some or all of the lost sales.

Rite-Hite, 56 F.3d at 1545 (*citing Kaufman Co. v. Lantech, Inc.,* 926 F.2d 1136, 1141 (Fed. Cir. 1991)).

IV. ARGUMENT

A. There Is No Basis For Centocor To Challenge The Admissibility Of The Independent Third-Party Data Ms. Davis Relies On In Her U.S. Lost Profits Analysis.

[redacted] Centocor's sole challenge to Ms. Davis's U.S. lost profits analysis is her alleged unfamiliarity with the WK data. Given record evidence to the contrary, Centocor's challenge is not legitimate, and in any event, concerns the weight of the evidence – not its admissibility.

Ms. Davis's report and deposition make clear that the PowerPoint presentations she considered contains WK data. [redacted] Federal Rule 702 allows experts, such as Ms. Davis, to rely on data in calculating her damages analysis. [redacted]

[redacted]

Contrary to Centocor's arguments (Motion at 10-13), this WK data – provided from a reliable and independent third-party data source – is wholly distinguishable from cases where an expert "simply accept[s] [plaintiff's own] projection[s] that their number of patients would increase from 7,000 in 2006 to 284,000 in 2007," *Diabetes Centers of America, Inc. v. Healthpia America, Inc.*, No. H-06-3457, 2008 U.S. Dist. LEXIS 10052, at *7 (S.D. Tex. Feb. 11, 2008), and where an expert "fail[s] to establish that the expert's numbers had any basis in reality" and "fail[s] to show that reasonable accountants would simply and blindly accept such numbers in formulating opinions" such that "the plaintiff is presenting its own estimation of damages in the guise of an expert opinion." *JRL Enters., Inc. v Procorp Assocs., Inc.*, No. 01-2893, 2003 U.S. Dist. LEXIS 9397, at *22-23 (E.D. La. June 3, 2003).

In this case, Ms. Davis relies on reliable commercial data from WK, a disinterested source. *Cf. Apple, Inc. v. Motorola, Inc.*, No. 11-8540, 2012 WL 1959560, at *4, 9 (N.D. Ill. May 22, 2012) (excluding expert opinion that "obtained the essential information . . . from an agent of the party rather than from a disinterested source"—notably the expert's opinion differed "by a factor of 140. The size of the disparity is a warning sign."). [redacted]

[redacted]

To the extent Centocor's motion is based on the fact that Abbott employees, rather than Ms. Davis herself, compiled the data relied on from the WK database, its challenge is also without merit. Neither common sense nor the Federal Rules requires that an expert have a hand in validating and sponsoring each and every fact or assumption that underlies the expert's opinion. Ms. Davis was no more required to herself generate the data on which she relied from the WK database than she was required to herself extract incremental costs from Abbott's accounting system or independently determine the market share figures on which both experts rely from the IMS data set. If Centocor wishes to attack Ms. Davis's opinion at trial on the fact that she did not personally undertake these data extraction activities, it is free to do so, but any such attack goes solely to weight, not admissibility. *See Allen*, 263 F.R.D. at 53 (citing *Ruiz-Troche*, 161 F.3d at 85).

[redacted]

To be sure, there is a dispute between the parties on the percentage of bio-naïve and bio-experienced patients, but that is also for the jury to sort out. [redacted] But Abbott does not ask the Court to usurp the role of the jury in deciding whose testimony is more reliable. That issue is for the jury.

B. Centocor's Challenge to Ms. Davis's O.U.S. Lost Profits Analysis Is Irrelevant In Light of Her Supplemental Report.

Centocor also seeks to exclude the O.U.S. lost profits analysis contained in Ms. Davis's May 2011 expert report. [redacted] Centocor's complaint is again directed to the factual underpinnings of Ms. Davis's methodology, which goes

to the weight of the proffered testimony, not to its admissibility. *See Crowe,* 506 F.3d at 18.

In any case, Centocor's complaint is irrelevant given Ms. Davis's supplemental report. Because of information she learned relating to O.U.S. patient switching among biologics in the course of preparing her supplemental report detailing Centocor's damages since her first report, Ms. Davis has adjusted her analysis to account for the switching data that has come to light. [redacted] n short, the O.U.S. lost profits analysis Ms. Davis conducts in her supplemental report mirrors her U.S. lost profits analysis, with the end result being an O.U.S. lost profits number that is favorable to Centocor.[6]

V. CONCLUSION

For the foregoing reasons, the Court should deny Centocor's motion to exclude the lost profits analyses of Abbott's damages expert, Ms. Davis.

Respectfully Submitted,

Dated: July 13, 2012

/s/ Robert J. Gunther, Jr.

Robert J. Gunther, Jr. (admitted *pro hac vice*)
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[6] This calculation is consistent with Centocor's own statements about O.U.S. switching. In its motion, [redacted] In any event, as discussed above, this factual dispute relating to the amount of damages is a question for the jury. *See Lucent*, 580 F.3d at 1310; *see also Rite-Hite*, 56 F.3d at 1545 (once the patentee shows there is a reasonable probability the patentee would have made the lost sales, it falls to the infringer to produce evidence of any lost sales that would not have been captured by the patentee).

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CERTIFICATE OF SERVICE

I certify that, on July 13, 2012, this document (filed through the ECF system) will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

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